UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,561	10/24/2003	Lone Jeppesen	6598.200-US	9137

23650 7590 09/04/2007

NOVO NORDISK, INC.
PATENT DEPARTMENT
100 COLLEGE ROAD WEST
PRINCETON, NJ 08540

EXAMINER	
SHIAO, REI TSANG	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
09/04/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nnipatent@novonordisk.com

Office Action Summary	Application No.	Applicant(s)	
	10/692,561	JEPPESEN ET AL.	
	Examiner	Art Unit	
	Rei-tsang Shiao, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 05/07/2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) 49-52 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-48 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 01/08/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the foreign application:

DENMARK 2002 01629 with a filing date 10/28/2002.

2. The petition filed under 37 C.F.R. 1.137(b), dated May 07, 2007, has been granted. The instant abandonment of this application dated July 06, 2006 has been withdrawn herein.

3. Claims 1-52 are pending in the application.

Responses to Amendment/Arguments

4. Since claims 1-48 have not been amended, the rejection of claims 1-48 under 35 U.S.C. 103(a) over Jeppesen et al. US 2004/0143006 A1 is maintained.

5. Since terminal disclaimers have not been filed to the Office, the provisional rejection of claims 1-48 under the obviousness-type double patenting over Jeppesen et al. co-pending application No. 10/654,699, or over Jeppesen et al. co-pending application No. 10/693,161, is maintained. Applicants are requested to file terminal disclaimers to overcome the rejection.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the instant compounds/compositions treating diabetes, does not reasonably provide enablement for the instant compounds/ compositions of formula (I) for treatment or prevention of conditions mediated by nuclear receptors without limitation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1988):

1) Nature of invention.

2) State of prior art.

3) Level of ordinary skill in the art.

4) Level of predictability in the art.

5) Amount of direction and guidance provided by the inventor.

6) Existence of working examples.

7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the instant case:

The nature of the invention

The nature of the invention of claims 46-47 is compounds/compositions of formula (I) with intent methods of use for treating or preventing conditions mediated by nuclear receptors without limitation.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat or prevent which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face. Brian et al. disclose PPAR agonists as agents treating diabetes, see US 6,787,556.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming compounds/composition of formula (I) effective against conditions mediated by nuclear receptors without limitation, which includes the treatment and prevention. As such, the specification fails to enable the skilled artisan to

use the compounds/compositions of the formula (I) to treat or prevent conditions mediated by nuclear receptors without limitation in a healthy subject. In addition, there is no proof that the claimed compounds/compositions of formula (I) have ever been administered to treat or prevent conditions mediated by nuclear receptors without limitation in a human or to an animal model.

In addition, there is no established correlation between *in vitro* activity and accomplishing treating or prevention of thrombosis or malignant tumors, *in vivo*, and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art would not be able to use the compounds/compositions of the formula (I) since there is no description of an actual method wherein conditions mediated by nuclear receptors without limitation in a host is treated or prevented.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compounds/compositions of formula (I) of the claims due to the unpredictability of the treatment or prevention of conditions mediated by nuclear receptors without limitation, the conditions mediated by nuclear receptors without limitation is known to have many obstacles that would prevent one of ordinary skill in the art from accepting preventive regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of

exemplary *in vitro* assay, i.e., luciferase assay, see pages 53-54. There are no working examples present for the treating or preventing conditions mediated by nuclear receptors without limitation by the administration of a pharmaceutical compounds/ compositions of the instant invention.

The breadth of the claims

The breadth of the claims is a pharmaceutical compounds/compositions of formula (I) effective against conditions mediated by nuclear receptors without limitation. Furthermore, the instant claims cover "conditions mediated by nuclear receptors" that are known to exist and those that may be discovered in the future, for which there is no enablement provided. Moreover, there is no reasonable basis for assuming the instant compounds/compositions of formula (I) embraced by the claims will share the same physiological properties.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what "conditions mediated by nuclear receptors" without limitation would be benefited (i.e., treated or prevented) by the administration of the pharmaceutical compounds/compositions of formula (I) of the instant invention and would furthermore then have to determine which of the claimed compounds/ compositions would provide treatment or prevention of conditions mediated by nuclear receptors" without limitation, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the pharmaceutical compounds/compositions of formula (I) of the instant claims for the treatment or prevention of "conditions mediated by nuclear receptors" without limitation. As a result necessitating one of skill to perform an exhaustive search for which conditions mediated by nuclear receptors" without limitation can be treated or prevented by what pharmaceutical compounds/compositions of formula (I) of the instant claims in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by deleting the intended use of the preamble "for the treatment and/or

prevention of conditions .....(PPAR)" of claim 46 and "for the treatment and/or prevention of conditions.....or obesity" of claim 47.

Objection

7. Claims 1-48 are objected to as containing non-elected subject matter, i.e., heteroaryl, heteroaralkyl, heteroarylene, heteroaralkoxy, oxazole, or isooxazole, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the pages 2-3 of the Office action dated 11/23/2005.

8. Claims 46-47 are objected to for being substantial duplicates of the claims from which they depend, also see claim 45. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. 706.03(k).

9. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims

or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

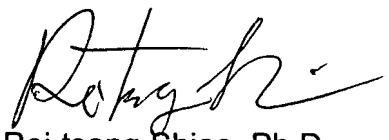
A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

August 24, 2007